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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,219	07/29/2003	Michael P. Schrom	03-002 (ANSI01-00014)	8297

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EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,219

Applicant(s)

SCHROM ET AL.

Examiner

Deborah Malamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3 and 45-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/29/03 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The examiner acknowledges the amendments received 25 August 2006. Claims 1 and 4-44 are cancelled. Claims 2 and 3 and new claims 45-50 are pending.

Specification

2. In view of the amendments, the examiner withdraws the objection to the specification.

Claim Objections

3. Claim 2 is objected to because of the following informalities: the claim reads "discontinuity is removed along a substantially length of the lead body," in line 20 of the claim. This should be changed to, for example, "along a substantial length of the lead body." Appropriate correction is required.
4. Claim 48 is objected to because it appears that a step was skipped in the section "wherein the forming step further comprises the steps of:" (lines 12-22). Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. In view of the amendments, and the cancellation of claims 1, 4, 7, 10, 22, 29 and 40, the examiner withdraws the rejections of these claims under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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7. In view of the cancellation of claims 1 and 4-44, and the amendments to claim 2, the examiner withdraws the rejection of claims 1, 3-4, 6-7, 9-10, 22-23, 26-29, 31 and 40 under 35 U.S.C. 102(b) as being anticipated by Kordis et al (U.S. 5,476,495); and of claims 4-5, 7-8, 10-11, 22, 24-25 and 40-41 as being anticipated by Cimino et al (U.S. 5,857,997). Rejection of the claims under new grounds is discussed below.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. In view of the cancellation of claims 1 and 4-44, and the amendments to claim 2, the examiner withdraws the rejection of claim 30 under 35 U.S.C. 103(a) as being unpatentable over Kordis et al (U.S. 5,476,495) in view of Cimino et al (U.S. 5,857,997).

10. Claims 2, 3 and 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cimino et al (U.S. 5,857,997) in view of Samson et al (U.S. 6,824,553). Regarding claims 2, 3, 47 and 50, Cimino discloses (col. 9, lines 57-58; col. 10, lines 4-10) an inner tubular member (25) formed of a thermoplastic elastomer and an outer jacket or coating (26) formed of a thermoplastic polymeric material. Within the inner tubular member are electrical conductors. These layers are formed using (col. 6, lines 62-68) a mandrel or stiffening member. Cimino also discloses the conductors connected to an electrical connector (53; col. 9, lines 29-33) on the proximal end of the handle in Figure 8, and to sensing and ablation electrodes (col. 5, lines 60-68). Cimino further discloses (col. 10, lines 38-48) a procedure for forming the catheter (10): "to complete the catheter body member, a heat shrinkable thermoplastic tubular member or

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sleeve which forms the outer jacket (26) is fitted onto the braided and impregnated reinforcing layer (27), and then a heat shrinkable tubular element (not shown) is fitted over the thermoplastic tube forming the outer jacket and the assembly is then heated by hot air to shrink the heat shrinkable tube and press the thermoplastic tube against the exterior of the reinforcing layer to secure the jacket thereto. Upon cooling, the heat shrinkable tube is stripped off and discarded and the catheter is then ground to the desired outer diameter." Cimino discloses the claimed invention except for formation of a lead body such that the inter-layer discontinuity is removed along a substantial length of the lead body after the cooling is performed. Samson however discloses (col. 2, lines 25-30) a catheter that "utilizes the concept of combining one or more polymeric tubes with a metallic braid comprising ribbons of a super-elastic alloy. The construction technique has the benefit of producing catheter sections having small overall diameters but with exceptional strength, resistance to kinking, and recovery from kinking (even in vivo) should such kinking occur." Samson further discloses (col. 7, lines 50-57) a catheter section made up of "an inner liner and an outer covering and having a super-elastic alloy ribbon braid located between the liner and the covering. The inner liner may be of a polymeric composition. The inner liner and the outer covering, should they be adjacent the braid and both polymeric, may be selected from polymers which are melt-compatible or melt-miscible with each other. In this way, adjacent polymeric layers hold fast to the braid located between them." The braid (4308; col. 18, lines 35-41) may be used as a conductor, and as such "it may be desirable to include a better conductor, e.g., gold, silver, copper, platinum, as one or more of the ribbons making up the braid.

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Similarly, the super-elastic alloy ribbons may be plated with such a conductor so to improve the conductivity of the braid/metallic tube assembly.” The polymer to be used as the outer covering (col. 11, lines 9-16) can be “extruded into a tubing of appropriate size and thickness and then cross-linked to raise the melt temperature of the resulting tubing. The tubing is then inflated and perhaps stretched to give the included polymer a specific molecular orientation. The tubing, so treated, may then be slipped over the combination of inner liner (204) and braid (206) and heat shrunk into place.” The polymer of the outer layer is also applied by placing a (col. 11, lines 50-55) polyurethane tubing over the braid, placing a polyethylene “shrink-wrappable” tubing over the polyurethane tubing, and heating the combination to pull the polyurethane down to the braid surface using the polyethylene tubing as the mover. The polyethylene is removed or left in place.” See Figure 2. Cimino and Samson both disclose methods of manufacturing implantable medical leads including two layers of tubing enclosing one or more conductors, by the process of applying heat shrink tubing. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Cimino’s implantable lead including electrodes with Samson’s fused-together layers in order to produce lead sections having improved strength over a small diameter.

11. Regarding claims 45 and 48, Samson discloses (col. 7, lines 61-63) “the super-elastic alloy braid is, in its most basic form, a braid comprising a number of small super-elastic alloy ribbons wound and treated in such a that the resulting braid is dimensionally stable and braided ribbons do not twist.” The examiner considers this to

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be a plurality of conductors. The outer layer and inner layer coat each of these conductors individually.

12. Regarding claims 46 and 49, the examiner considers the conductors shown in Samson's Figure 2 to be helically placed around the inner layer of the extrusion material.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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